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**ORIGINAL
FILED**
SEP 21 2007
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

0 07 4911

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

EMC

20 STATE OF CALIFORNIA *ex rel.* JAYDEEN)
VICENTE and JAYDEEN VICENTE)
21 Individually,)
22 Plaintiffs,)
23 v.)
24 ELI LILLY AND COMPANY,)
25 Defendant.)
26)

Case No.

NOTICE OF REMOVAL

NOTICE OF REMOVAL

1 TO THE CLERK OF THE ABOVE-ENTITLED COURT:

2 PLEASE TAKE NOTICE that defendant Eli Lilly and Company, Inc. ("Lilly") hereby
3 removes to this Court the above-captioned case, originally filed in the Superior Court of California
4 in and for the City and County of San Francisco, on federal question grounds pursuant to 28 U.S.C.
5 §§ 1331, § 1367, and 1441(b).

6 As explained in detail below, this Court has original jurisdiction under 28 U.S.C. § 1331 in
7 this case because Plaintiffs expressly allege violations of, and "liability under," the federal False
8 Claims Act, 31 U.S.C § 3729. *See* Compl. ¶¶ 64, 210-211 & p.43. In addition, and independent of
9 Plaintiffs' claims under the federal False Claims Act, this Court also has jurisdiction of Plaintiffs'
10 state law claims for violation of the California False Claims Act under 28 U.S.C. § 1331 because
11 those claims "necessarily depend[] on resolution of a substantial question of federal law." *Franchise*
12 *Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983); *Grable & Sons Metal*
13 *Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005).

14 In support of removal, Lilly states as follows:

15 1. This action was originally filed on May 11, 2007 *under seal* in the Superior Court of
16 the State of California in and for the City and County of San Francisco, captioned as *State of*
17 *California ex. rel. Jaydeen Vicente and Jadeen Vicente Individually, Plaintiffs, v. Eli Lilly and*
18 *Company, Defendant*, Case Number CGC-07-463338.

19 2. On July 10, 2007, the State of California declined to intervene in this action.

20 3. Plaintiffs served Lilly with a copy of the Complaint and Summons on August 22,
21 2007. This Notice of Removal is timely, having been filed within thirty (30) days of service. *See* 28
22 U.S.C. § 1446(b).

23 4. This action involves allegations regarding the FDA-approved medicine Zyprexa®,
24 which allegations are also made in multidistrict litigation captioned *In re Zyprexa Products Liability*
25 *Litigation*, MDL No. 1596, pending before the Honorable Jack B. Weinstein in the United States
26 District Court for the Eastern District of New York. Similar Zyprexa-related suits against Lilly by
27 several States are already pending in MDL No. 1596.

5. Lilly intends to file shortly a Motion to Stay All Proceedings Pending Transfer by the Judicial Panel on Multidistrict Litigation ("JPML"), asking this Court to stay this action pending its transfer to MDL No. 1596. A stay will conserve the Court's and the parties' resources and prevent inconsistent rulings on global issues that arise repeatedly in actions involving Zyprexa. For this reason, courts in more than 100 other cases have granted stays pending transfer of Zyprexa-related actions to MDL No. 1596

6. True and correct copies of the Civil Case Cover Sheet, Proof of Service of Summons, State of California's Notice of Election to Decline Intervention Pursuant to Government Code Section 12652(c)(8)(D)(ii), Confidential Cover Sheet – False Claims Action, Civil Case Cover Sheet, Notice to Plaintiff of Case Management Conference, Stipulation to Alternative Dispute Resolution, and Judicial Mediation Program and Alternative Dispute Resolution (ADR) Information Package, Service of Process Summary Transmittal Form, Confidential Cover Sheet – False Claims Action, Proof of Service of Relators' Statement on the Office of the Attorney General in Sacramento, Proof of Service of Relators' Statement on the Office of the Attorney General in San Francisco, Proof of Service of Complaint For Damages [Under Seal]; Civil Case Cover Sheet; Confidential Cover Sheet – False Claims Action; Confidential Cover Sheet – False Claims Action on the Office of the Attorney General in Sacramento, and Complaint for Damages served on Lilly are attached hereto as Exhibit A. Exhibit A constitutes all process, pleadings or orders served on Lilly as of the date of filing this Notice of Removal.

7. Lilly will be filing a true and correct copy of this Notice of Removal with the Superior Court of California in and for the City and County of San Francisco and will serve the same on all parties of record pursuant to 28 U.S.C. § 1446(d).

THE COMPLAINT

8. Plaintiffs' Complaint alleges that Lilly illegally promoted the drug Zyprexa® for indications not approved by the United States Food and Drug Administration ("FDA") in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), and federal regulations promulgated thereunder. *See, e.g.,* Compl. ¶¶ 37-51, 54-63.

9. The Complaint further alleges that Lilly violated the federal Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320, *et seq.* (“AKS”), by allegedly paying to physicians “illegal remuneration” in the forms of “‘speaker fees,’ honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa” to patients. Compl. ¶¶ 198 (p. 40, 42)¹, 192-201 (pp. 38-40), 202-211 (pp. 43-44).²

10. Plaintiffs surmise that, a result of Lilly’s alleged violations of *federal law* – including Lilly’s alleged “off-label” promotion of Zyprexa in violation of the FDCA and its alleged illegal payments to physicians and others in violation of AKS – false claims for reimbursement were submitted to *both* the federal Medicare and state Medicaid programs. *See, e.g.*, Compl. ¶ 50 (alleging that numerous allegedly false claims were submitted to the “Medicaid/Medicare programs for reimbursement”).

11. According to Plaintiffs’ Complaint, these claims were “false” because *federal law* precluded reimbursement of claims that did not meet the federal definition of “covered outpatient drug” and each of the individual uses for which the drug was prescribed (and a claim for reimbursement submitted) was not “approved by the FDA, or supported by one of the three specifically identified compendia.” Compl. ¶ 39 (citing 42 U.S.C.A. §§ 1396r-8, 1396(k)(3), 1396(k)(6) & 1396(g)(1)(b)(i)). Plaintiffs contend that the alleged submission of these claims that were not eligible for reimbursement constitutes “[p]redicate Acts Giving Rise to Liability Under the State and Federal False Claim Acts.” Compl. at p.43 (underline added, bold in original).

12. Based on these allegations (which are incorporated by reference in each of Plaintiffs’ Causes of Action), the Complaint purports to allege the following four counts, entitled: (1) First Cause of Action, California False Claims Act, California Government code § 12650 *et seq.*; (2) Second Cause of Action, Conspiracy to Submit False Claims in Violation of the California False Claims Act, California Government Code § 12651(a)(3); (3) Third Cause of Action, Violation of

¹ The Complaint contains two different versions of paragraphs 194-208 (pp. 39-44). Citations to both paragraph and page therefore have been included where necessary to eliminate any confusion.

² Lilly denies all of Plaintiffs’ allegations of wrongdoing.

1 Business & Professions Code § 17200; and (4) Fourth Cause of Action, Violation of Business &
 2 Professions Code § 17500.

3 13. Plaintiffs seek treble damages, civil penalties and fines, attorney fees, and costs of
 4 suit.

5 FEDERAL QUESTION JURISDICTION

6 **A. This Court Has Original Jurisdiction Over Plaintiffs' Federal False Claims Act Claims**

7 14. Title 28 U.S.C. § 1441(b) provides in pertinent part:

8 Any civil action of which the district courts have original jurisdiction
 9 founded on a claim or right arising under the constitution, treaties or
 10 laws of the United States shall be removable without regard to the
 citizenship or residence of the parties.

11 15. Although Plaintiffs have artfully avoided enumerating or captioning their federal
 12 False Claims Act allegations as one of their four Causes of Action, Plaintiffs' Complaint expressly
 13 alleges liability under the federal False Claims Act. *See* Compl. at p. 43 (alleging that Lilly is liable
 14 "[u]nder the State and Federal False Claim Acts") (emphasis added); ¶ 210 (alleging "Lilly's liability
 15 under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act . . .") (emphasis added); ¶ 211
 16 (alleging "Lilly's conduct is also punishable under . . . the Federal False Claims Act") (emphasis
 17 added); ¶ 64 (citing federal False Claims Act).³

18 16. Because Plaintiffs expressly allege violations of the federal False Claims Act, this
 19 Court has federal question jurisdiction over those claims, and Plaintiffs' entire Complaint is properly
 20 removable to this Court. *See* 28 U.S.C. § 1367 (providing supplemental jurisdiction over all related
 21 state law claims).

22
 23
 24
 25 ³ The fact that Plaintiffs' federal False Claims Act claims are procedurally improper or wholly without merit
 26 does not defeat removal jurisdiction. *See* Schwarzer, Tashima & Wagstaffe, California Practice Guide – Federal Civil
 27 Procedure Before Trial §2:700 at 2D-48 (The Rutter Group 2007) ("If plaintiff is asserting a federal claim (whether or
 28 is meritless") (citing *Barracough v. ADP Automotive Claims Services*, 818 F. Supp. 1310, 1312 (N.D. Cal. 1993) ("A
 plaintiff should not be permitted to effectuate remand by pointing out the flaws in her own complaint, in effect arguing
 for dismissal of that claim.")).

B. Plaintiffs' California False Claims Act Allegations Necessarily Depend on Resolution of Disputed and Substantial Federal Questions

17. Independent of Plaintiffs' federal False Claims Act claims, this Court also has federal-question jurisdiction over Plaintiffs' state law Claims for violation of the California False Claims Act (the First and Second Causes of Action) under 28 U.S.C. § 1331 and the principles set forth in *Grable*, 545 U.S. 308.

18. The United States Supreme Court's decision in *Grable* held that federal question jurisdiction did not require the plaintiff to have asserted a violation of a federal statute providing a private parallel right of action.⁴ Rather, under *Grable*, a case asserting only state law causes of action is removable if it raises a substantial federal question, "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *See Grable*, 545 U.S. at 314-320.

19. As more fully explained below, Plaintiffs' claims require construction and application of three areas of federal law: (1) the FDCA, 21 U.S.C. § 301, *et seq.* and implementing federal regulations which govern approval of new drugs and regulate prescription drug manufacturers' promotional statements, including all aspects of warnings in labeling and advertising; (2) the federal Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320, *et seq.* ("AKS"), which prohibits certain remuneration with respect to the sale of prescription drugs; and (3) federal Medicaid law, which determines the drugs for which a State can decline to pay, *see* 42 U.S.C. §§ 1396r-8(d)(B), (d)(4).

20. In *In re Zyprexa Prod. Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the federal court held that it had federal question jurisdiction over virtually identical state law claims by Louisiana involving Lilly's marketing of Zyprexa and Louisiana's payments for Zyprexa and under its Medicaid program. The court found that references in the complaint to federal funding provisions and laws and allegations related to marketing for non-FDA approved uses demonstrate "a core of

⁴ *Grable* limited *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986), to the extent *Merrell Dow* implied or held that a federal cause of action was required to remove a pharmaceutical product liability case.

substantial issues” that were federally oriented. *Id.* at 172-73; *see also West Virginia v. Eli Lilly and Company*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (denying motion to remand in action by Mississippi involving substantially same allegations).

21. Similarly, in a case involving Medicaid drug pricing, this Court in *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005) invoked federal question jurisdiction under *Grable* because the plaintiff’s state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. *Id.* at 1031. In concluding that Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is “the importance of the federal issue.” *Id.* at 1027. The court noted that “[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme.” *Id.*

22. Because Plaintiffs’ claims in this case, like those in *Grable*, *In re Zyprexa*, *West Virginia* and *County of Santa Clara*,⁵ will necessarily involve the resolution of disputed and substantial federal questions in the context of three complex and inter-related federal regulatory schemes, this Court has federal question jurisdiction

1. Plaintiffs’ Right to Relief Requires Resolution of Disputed and Substantial Issues Under the FDCA

23. At the heart of this case are claims based on alleged violations of the FDCA by Lilly, in particular, that Lilly illegally promoted Zyprexa for various uses that are allegedly “off-label” and

⁵ Although other federal courts have recently declined to exercise removal jurisdiction in Zyprexa-related false claims suits, those cases are all distinguishable because, unlike Plaintiffs’ allegations herein, the plaintiffs in those cases did not allege violations of the *federal* False Claims Act. *See Alaska v. Eli Lilly & Co.*, 2006 WL 2168831 (D. Alaska July 28, 2006); *Utah v. Eli Lilly & Co.*, 2007 WL 2482397 (D. Utah Sept. 4, 2007); *South Carolina v. Eli Lilly & Co.*, 2007 WL 2261693 (D. S.C. Aug. 3, 2007). The Utah decision is further distinguishable because, unlike in this case, there were independent state-law bases for deciding plaintiff’s state False Claims Act claims, which relied on state-law definitions of, for example, “medically necessary.” *See, e.g., Utah*, 2007 WL 2482397 at *4 (noting that plaintiff’s claims were based in part on two provisions of Utah law and concluding that “[g]iven these multiple bases, resolution of [the state false claims act cause of action] does not hinge solely on a federal question.”) Here, however, the Complaint does not allege any cognizable standard of California law as a basis for its claims under the California False Claims Act. Rather, resolution of Counts I and II will turn entirely on disputed and substantial federal questions. *See*, ¶¶ 17-37.

not “medically accepted indications,” both concepts defined according to federal law, thereby causing harm to California.⁶ For example, the Complaint alleges that by illegally marketing Zyprexa for off-label uses, Lilly caused physicians and pharmacies to request Medicaid reimbursement for uses for which Zyprexa was not eligible under the Medicaid Program. Compl. ¶¶ 49-50. The same basic allegations were made by the States of Louisiana, West Virginia and Mississippi against Lilly with respect to Zyprexa. See *In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005); *West Virginia v. Eli Lilly and Company*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007); *Hood v. Eli Lilly and Company*, 2007 WL 1601482 (E.D.N.Y. June 5, 2007). Lilly disputes these allegations, including specifically the allegation that it violated the FDCA by marketing the drugs for uses that are not medically necessary or indications that are not medically accepted.

24. As a currently marketed prescription drug, Zyprexa is subject to extensive regulation by the FDA. The FDCA requires the FDA to ensure that “drugs are safe and effective” for their intended uses, 21 U.S.C. § 393(b)(2)(8), in part by “promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products.” 21 U.S.C. § 393(b)(1). The Commissioner of the FDA has the authority to promulgate regulations to enforce the FDCA, which are codified in the *Code of Federal Regulations*, 21 C.F.R. § 1, *et seq.* See 21 U.S.C. § 371(a).

25. Promotional claims to physicians about Zyprexa are regulated by the FDA to ensure that the claims are in compliance with the FDCA and FDA implementing regulations. Of particular relevance, the FDA reviews promotional materials to assure that they do not create new “intended uses” for which adequate directions are, in the absence of FDA approval of the drug for that use, lacking, thereby violating Section 502(f)(1) of the FDCA, 21 U.S.C. § 352(f)(1). The FDA also reviews promotional labeling to assure that it does not recommend or suggest conditions of use that would make the drug an “unapproved new drug” under section 505(a), 21 U.S.C. § 355(a), the distribution of which in interstate commerce would violate federal law. Detailed regulations

⁶ Promotion for non-FDA approved uses is “a promotion that violates the [FDA’s] strictures on off-label marketing.” *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003).

1 implementing these general provisions, as well as a general statutory prohibition against labeling that
2 is false or misleading "in any particular," appear in 21 C.F.R. § 201 and 202. *See also* 21 C.F.R. §§
3 310 and 314 ("new drug" and "new drug" approval requirements).

4 26. As an integral part of this comprehensive statutory and regulatory scheme governing
5 the content of promotional claims, the FDA has crafted a number of rules and policies expressly
6 allowing manufacturers to engage in the non-promotional dissemination of information to physicians
7 about new drugs and new uses of approved drugs. FDA regulations expressly permit scientific
8 exchange by manufacturers and their representatives about investigational new drugs and
9 investigational uses of approved new drugs. *See* 21 C.F.R. 312.7(a). The FDA has also recognized
10 that manufacturer dissemination of scientific information – through reprints of medical journal
11 articles, support of CME, and responses to unsolicited requests for information – is not only allowed
12 but entirely appropriate and, indeed, a necessary corollary of the agency's long-standing policy of
13 non-interference in physician decisions to prescribe approved drugs off-label as part of medical
14 practice. *See, e.g.,* 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) ("The agency has recognized the
15 need among health care professionals for peer review and dissemination of the latest significant
16 scientific data and information on drugs and devices in scientific journals."); 21 C.F.R. § 312.7 (pre-
17 approval promotion ban "is not intended to restrict the full exchange of scientific information
18 concerning the drug, including dissemination of scientific findings in scientific or lay media.").
19 Taken together, the content regulatory provisions of the FDCA and FDA regulations describe above,
20 and the various policies established by FDA to facilitate scientific exchange about off-label uses,
21 comprise a careful federal system balancing the scientific informational needs of physicians and the
22 public interest in assuring that commercial communications are truthful and non-misleading. And
23 above and beyond this, the courts have made clear that another source of federal law – the
24 Constitution – limits the government's ability to restrict the dissemination of truthful non-misleading
25 information concerning their products. *See, e.g., Washington Legal Found. v. Friedman*, 13 F. Supp.
26 2d 51 (D.D.C. 1998), vacated on other grounds, *Washington Legal Found. v. Henney*, 128 F. Supp.

2d 11 (D.D.C. 2000). Allegations regarding any specific communication must be resolved with reference to this carefully balanced complex of *federal* law.

27. The FDA's responsibility to regulate prescription drugs sold in the United States, and to enforce laws with respect to such drugs, inclusive of the precise content and format of prescription drug labeling (e.g., the instructions, warning, precautions, adverse reaction information provided by manufacturers, and marketing materials), is plenary and exclusive. *See* 21 U.S.C. § 301, *et seq.*

28. Plaintiffs have made alleged violations of federal law a critical element of one or more of its claims against Lilly. Accordingly, Plaintiffs' claims regarding the safety, labeling, promotion and marketing of Zyprexa necessarily raise substantial federal questions by requiring the Court to interpret the meaning of the FDCA and its implementing regulations.

2. Plaintiffs' Right to Relief Requires Resolution of Disputed and Substantial Issues Under the AKS

29. Plaintiffs' False Claims Act claims also require resolution of disputed and substantial issues under the federal AKS because they require resolution of whether specific items of remuneration allegedly paid by Lilly would constitute a violation of the federal kick-back prohibitions. For example, while Plaintiffs allege at paragraph 198 of the Complaint that Lilly allegedly paid kick-backs in the form of "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa," Plaintiffs elsewhere acknowledge (Compl. ¶ 200, p. 40), as they must, that not every payment made to a physician violates AKS. To the contrary, the federal AKS only prohibits payments meant to "induce" the recipient (1) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (2) to purchase or lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program. Compl. ¶ 192 (quoting 42 U.S.C. § 1320a-7b(b)(2)(A) & (B)).

30. Although Plaintiffs conclude that such remuneration was, in fact, paid, thereby resulting in false claims being filed with the government, Plaintiffs cannot dispute (and indeed

1 allege) that at least the stated purposes of those payments were legitimate, including speaker fees,
2 honoraria, and educational grants. Compl. ¶ 198 (p. 40, 42) (alleging that “Lilly paid, and physicians
3 accepted, cash payments thinly-veiled as ‘speaker fees,’ honoraria, and . . . educational grants”).
4 Calling them “thinly-veiled,” however, only begs the question. In each instance, Plaintiffs must
5 prove and the Court examine the individual circumstances of the payment and services provided to
6 determine if there was a violation of the AKS. Furthermore, there are statutory exceptions and
7 regulatory safe harbors under the federal AKS that expressly protect certain payments, including
8 payments provided by pharmaceutical manufacturers to both physician and non-physician service
9 providers, that comply with the safe harbor requirements. Indeed, depending on the circumstances
10 of the payments and the services provided, the personal services safe harbor, 42 C.F.R. §
11 1001.952(d), may in fact insulate as a matter of law many of the payments Plaintiffs allege were
12 improper. Determination of the alleged impropriety of these payments thus involves an analysis of
13 complex *federal* statutes and regulations.

14 31. California’s Health & Safety Code §§ 119400-02 (also cited by Plaintiffs) does not
15 provide an alternative and independent state law basis for imposing False Claims Act liability.
16 Unlike the AKS, the California statutes do not impose any substantive limits on remuneration to
17 health care providers; rather, as Plaintiffs’ allegations make clear, they merely require manufacturers
18 to establish compliance programs which implement a self-imposed and self-defined “‘specific
19 annual dollar limit on gifts, promotional materials, or items or activities” that the manufacturer may
20 provide to medical or health care professionals.” Compl. ¶ 206 (p. 41) (quoting Calif. Health &
21 Safety Code § 119402(c)-(d)). Plaintiffs do not allege that Lilly failed to adopt such a compliance
22 policy or failed to adhere to the policy it adopted. Moreover, nothing in that compliance policy is in
23 any way tied to a claim for reimbursement, which is, of course, a necessary element for liability
24 under the California False Claims Act.

1 **3. Plaintiffs' Right to Relief Requires Resolution of Disputed and**
2 **Substantial Issues Under Federal Medicaid Law**

3 32. Plaintiffs' claims also raise disputed and substantial questions of federal law under
4 the Social Security Act because they depend upon the interpretation and application of federal
5 statutory provisions governing a State's reimbursement for prescription medicines. Plaintiffs'
6 Complaint admits as much. *See* Compl. ¶ 37 (alleging that "[f]ederal statutes and regulations restrict
7 the drugs and drug uses that the federal and state governments will pay for Medicaid programs."). In
8 particular, the Complaint alleges that, under federal law, reimbursement of Medicaid claims is
9 limited to "covered outpatient drug[s]," defined as "those drug[s] prescribed to treat medically
10 excepted [sic] indications." Compl. ¶ 39 (citing 42 U.S.C. § 1396(k)(3). According to the
11 Complaint, federal law further defines a "medically accepted indication" as "any use approved by
12 the FDA, or supported by one of the three specifically identified compendia." Compl. ¶ 39 (citing
13 42 U.S.C.A. § 1396(k)(6)).

14 33. These federal definitions and rules are indispensable to Plaintiffs' state law causes of
15 action for violation of the California False Claims Act. For example, Plaintiffs allege that
16 "[w]hether the use of a drug is medically necessary was material to Medicaid's decision to reimburse
17 for prescription" (Compl. ¶ 42), however, "[u]se of Zyprexa, for example, for dementia, or for
18 anxiety or depression in the elderly is not supported by the compendia as medically safe and
19 effective, and therefore should not have been covered by the State of California's Medicaid
20 programs." Compl. ¶¶ 42-43.

21 34. The federal Medicaid program authorizes federal grants to states to provide medical
22 assistance to low income individuals. 42 U.S.C. § 1396, *et seq.* "Although participation in the
23 program is voluntary, participating States must comply with certain requirements imposed by the
24 Act and regulations promulgated by the Secretary of Health and Human Services." *Wilder v.*
25 *Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990).

26 35. Federal law requires the States, subject to certain narrow exceptions, to reimburse
27 FDA-approved prescription drugs of any manufacturer that has entered into and complies with a
28

1 rebate agreement with the Secretary of Health and Human Services, 42 U.S.C. § 1396r-8(d)(4)(B).
 2 Thus, California is required under federal law to reimburse for drugs, such as Zyprexa, if the
 3 manufacturer complies with federal requirements.

4 36. The only time a state can exclude from its formulary (or preferred drug list) a covered
 5 outpatient drug subject to a rebate agreement is “with respect to the treatment of a specific disease or
 6 condition for an identified population . . . if, based on the drug’s labeling . . . the excluded drug does
 7 not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness,
 8 or clinical outcome of such treatment for such population over other drugs included in the formulary
 9 and there is a written explanation (available to the public) of the basis for the exclusion.” 42 U.S.C.
 10 § 1396r-8(d)(4)(D). Moreover, even a decision to require prior authorization must satisfy federally-
 11 mandated requirements. 42 U.S.C. §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with
 12 regard to Medicaid coverage of an FDA-approved drug is subject to strict federal mandates.

13 4. The Federal Interest in Providing a Forum

14 37. The federal government has a strong interest in having a federal court decide several
 15 of the issues in this case. Among these issues are (1) whether any conduct of Lilly, including the
 16 alleged marketing of Zyprexa for unapproved or non-medically necessary uses, violated any federal
 17 laws or regulations related to the labeling and marketing of drugs; (2) whether Lilly’s alleged
 18 dissemination of information about such uses was protected by the First Amendment of the United
 19 States Constitution; (3) whether the federal AKS prohibited certain payments made by Lilly to
 20 physicians for, *inter alia*, speaker fees, honoraria, and educational grants; and (4) whether federal
 21 Medicaid law permitted reimbursement for the uses in which Zyprexa was prescribed.

22 38. Plaintiffs’ claims may be vindicated or defeated only by construction of federal
 23 statutes and regulations. The availability of a federal forum to protect the important federal interests
 24 at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial
 25 and disputed federal issues that lie at the heart of this case would not “disturb any congressionally
 26 approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314.

27 * * * * *

1 WHEREFORE, Lilly notices the removal of this case to the United States District Court for
2 the Northern District of California pursuant to 28 U.S.C. §§ 1331, 1367, & 1441, et seq.

3
4 Dated: September 21, 2007

SIDLEY AUSTIN LLP

5
6 By 

7 Geoffrey M. Edgar

8 Attorneys For Defendant
9 ELI LILLY AND COMPANY
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PROOF OF SERVICE

I am employed in the County of San Francisco, State of California. I am over the age of 18 and not a party to the within action. My business address is Sidley Austin LLP, 555 California Street, San Francisco, California 94104.

On September 21, 2007, I served the foregoing document(s) described as **NOTICE OF REMOVAL** on all interested parties in this action as follows (or as on the attached service list):

- ☒ (U.S. MAIL) I served the foregoing document(s) by U.S. Mail, as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's business practice for collection and processing of correspondence for mailing. Under that practice, the correspondence would be deposited in the United States Postal Service on that same day in the ordinary course of business, with postage thereon fully prepaid.
- ☐ (U.S. EXPRESS MAIL) I served the foregoing document(s) by Express Mail, as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's practice for collection and processing of correspondence for mailing via Express Mail. Under that practice, the Express Mail would be deposited in the United States Postal Service on that same day in the ordinary course of business, with Express Mail postage thereon fully prepaid.
- ☐ (FACSIMILE) I caused the foregoing document(s) to be served by facsimile transmission from facsimile machine number (415) 772-7400 to the interested party at the facsimile telephone numbers shown. Each transmission was reported as complete and without error. A transmission report was properly issued by the sending facsimile machine for each interested party served.
- ☐ (FEDERAL EXPRESS) I served the foregoing document(s) by Federal Express as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's practice for collection and processing of correspondence for mailing via Federal Express (an express service carrier which provides overnight delivery). Under that practice, the sealed, addressed envelope(s) are delivered to an authorized courier or driver authorized by Federal Express the same date they are collected and processed, with all charges paid.
- ☐ (HAND DELIVERY) I caused the document(s) to be delivered by hand by a courier service to the addressee(s) shown above unless otherwise noted.
- ☐ (E-MAIL) I caused the document(s) to be delivered by e-mail to each interested party as shown above.
- ☐ (LEXIS NEXIS) I caused the document(s) to be delivered by e-mail by Lexis Nexis File & Serve to each interested party as shown above.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on September 21, 2007, at San Francisco, California.

By:


Gabriela Rodriguez

SERVICE LIST

Nancy Hirsh, Esq., State Bar No. 49091 (By Hand Delivery and U.S. Mail)
Mark E. Burton, Jr. Esq., State Bar No. 178400
Rachel Abrams, Esq., State Bar No. 209316
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Mark Zahner, Chief Prosecutor, State Bar No. 137732
Brian V. Frankel, Supervising Attorney General, State Bar No. 116802
1455 Frazee Road, Suite 315
San Diego, CA 92108
(619) 688-6065

Edmund G. Brown, Jr., Attorney General of the State of California
Office of the Attorney General
1300 "I" Street
P.O. Box. 944255
Sacramento, CA 94244-2550

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, telephone number, and address): NANCY HERSH, ESQ. HERSH & HERSH, A Professional Corp. 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102-6396 TELEPHONE NO.: (415) 441-5544 FAX NO.: ATTORNEY FOR (Name): Plaintiff		CALIFORNIA STATE BAR 49091		FOR COURT USE ONLY <div style="font-size: 2em; font-weight: bold; margin: 10px 0;">FILED</div> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> IMAGED AUG 28 2007 </div> <div style="text-align: center;"> San Francisco County Superior Court MAY 11 2007 </div> </div> <div style="text-align: right; margin-top: 10px;"> GORDON PARK-LI, Clerk BY: <u>Param Nath</u> Deputy Clerk </div>	
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: San Francisco, CA 94102 CITY AND ZIP CODE: BRANCH NAME: Unlimited Jurisdiction					
CASE NAME: VICENTE v. ELI LILLY AND COMPANY					
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000) <input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)			Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)		CASE NUMBER: CGC-07-463338 JUDGE: DEPT:

Items 1-5 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PVPD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PVPD/WD (23) Non-PVPD/WD (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PVPD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input checked="" type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
--	--	---

2. This case ☐ is ☒ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- | | |
|--|--|
| a. <input type="checkbox"/> Large number of separately represented parties | d. <input type="checkbox"/> Large number of witnesses |
| b. <input type="checkbox"/> Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve | e. <input type="checkbox"/> Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court |
| c. <input type="checkbox"/> Substantial amount of documentary evidence | f. <input type="checkbox"/> Substantial postjudgment judicial supervision |
3. Type of remedies sought (check all that apply):
 a. ☒ monetary b. ☐ nonmonetary; declaratory or injunctive relief c. ☐ punitive
4. Number of causes of action (specify): **4**
5. This case ☐ is ☒ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)
- Date: **May 11, 2007**

RACHEL ABRAMS

(TYPE OR PRINT NAME)


(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

POS-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State, number, and address): NANCY HERSH, ESQ. HERSH & HERSH, A Professional Corp. 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102-6396 TELEPHONE NO.: (415) 441-5544 FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR (Name): Plaintiff		FOR COURT USE ONLY FILED San Francisco County Superior Court MAY 21 2007 GORDON PARK-LI, Clerk  Deputy Clerk
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: San Francisco, CA 94102 CITY AND ZIP CODE: BRANCH NAME: Unlimited Jurisdiction		
PLAINTIFF/PETITIONER: JAYDEEN VICENTE DEFENDANT/RESPONDENT: ELI LILLY AND COMPANY		CASE NUMBER: CGC-07-463338
PROOF OF SERVICE OF SUMMONS		Ref. No. or File No.:

(Separate proof of service is required for each party served.)

1. At the time of service I was at least 18 years of age and not a party to this action.
2. I served copies of:
 - a. ☒ summons
 - b. ☒ complaint
 - c. ☐ Alternative Dispute Resolution (ADR) package
 - d. ☒ Civil Case Cover Sheet (served in complex cases only)
 - e. ☐ cross-complaint
 - f. ☒ other (specify documents): **Confidential Cover Sheet-Complaint; Confidential Cover Sheet-Civil Case Cover Sheet**
3. a. Party served (specify name of party as shown on documents served): **Attorney General of California**
 - b. ☐ Person (other than the party in item 3a) served on behalf of an entity or as an authorized agent (and not a person under item 5b on whom substituted service was made) (specify name and relationship to the party named in item 3a):
4. Address where the party was served: **1300 "I" Street, P.O. Box 944255, Sacramento, CA 94244-2550**
5. I served the party (check proper box)
 - a. ☐ by personal service. I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on (date): (2) at (time):
 - b. ☐ by substituted service. On (date): at (time): I left the documents listed in item 2 with or in the presence of (name and title or relationship to person indicated in item 3):
 - (1) ☐ (business) a person at least 18 years of age apparently in charge at the office or usual place of business of the person to be served. I informed him or her of the general nature of the papers.
 - (2) ☐ (home) a competent member of the household (at least 18 years of age) at the dwelling house or usual place of abode of the party. I informed him or her of the general nature of the papers.
 - (3) ☐ (physical address unknown) a person at least 18 years of age apparently in charge at the usual mailing address of the person to be served, other than a United States Postal Service post office box. I informed him or her of the general nature of the papers.
 - (4) ☐ I thereafter mailed (by first-class, postage prepaid) copies of the documents to the person to be served at the place where the copies were left (Code Civ. Proc., § 415.20). I mailed the documents on (date): from (city): or ☐ a declaration of mailing is attached.
 - (5) ☐ I attach a declaration of diligence stating actions taken first to attempt personal service.

Page 1 of 2

PROOF OF SERVICE OF SUMMONS

PLAINTIFF/PETITIONER: JAYDEE CENTE	C	NUMBER: CGC-07-463338
DEFENDANT/RESPONDENT: ELI LILLY AND COMPANY		

5. c. ☐ by mail and acknowledgment of receipt of service. I mailed the documents listed in item 2 to the party, to the address shown in item 4, by first-class mail, postage prepaid,
- (1) on (date): (2) from (city):
- (3) ☐ with two copies of the Notice and Acknowledgment of Receipt and a postage-paid return envelope addressed to me. (Attach completed Notice and Acknowledgement of Receipt.) (Code Civ. Proc., § 415.30.)
- (4) ☐ to an address outside California with return receipt requested. (Code Civ. Proc., § 415.40.)
- d. ☒ by other means (specify means of service and authorizing code section):
by certified mail, return receipt requested, pursuant to Government Code §12652(c)(3)

☐ Additional page describing service is attached.

6. The "Notice to the Person Served" (on the summons) was completed as follows:

- a. ☐ as an individual defendant.
- b. ☐ as the person sued under the fictitious name of (specify):
- c. ☐ as occupant.
- d. ☐ On behalf of (specify):

under the following Code of Civil Procedure section:

- | | |
|---|---|
| <input type="checkbox"/> 416.10 (corporation) | <input type="checkbox"/> 415.95 (business organization, form unknown) |
| <input type="checkbox"/> 416.20 (defunct corporation) | <input type="checkbox"/> 416.60 (minor) |
| <input type="checkbox"/> 416.30 (joint stock company/association) | <input type="checkbox"/> 416.70 (ward or conservatee) |
| <input type="checkbox"/> 416.40 (association or partnership) | <input type="checkbox"/> 416.90 (authorized person) |
| <input type="checkbox"/> 416.50 (public entity) | <input type="checkbox"/> 415.46 (occupant) |
| | <input type="checkbox"/> other: |

7. Person who served papers

- a. Name: Judy Olasov
- b. Address: 601 Van Ness Avenue, Suite 2080, San Francisco, CA 94102
- c. Telephone number: (415) 441-5544
- d. The fee for service was: \$ -0-
- e. I am:

- (1) ☒ not a registered California process server.
- (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
- (3) ☐ a registered California process server:
- (i) ☐ owner ☐ employee ☐ independent contractor.
- (ii) Registration No.:
- (iii) County:

8. ☒ I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

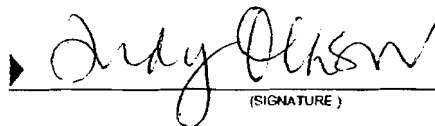
or

9. ☐ I am a California sheriff or marshal and I certify that the foregoing is true and correct.

Date: May 21, 2007

JUDY OLASOV

(NAME OF PERSON WHO SERVED PAPERS/SHERIFF OR MARSHAL)



(SIGNATURE)

SENDER: COMPLETE THIS SECTION

- Complete Items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Office of the Attorney General
 1300 "I" Street
 P.O. Box 944255
 Sacramento, CA 94244-2550

COMPLETE THIS SECTION ON DELIVERY**A. Signature**

Matthew Woods

☐ Agent☐ Addressee**B. Received by (Printed Name)****C. Date of Delivery****D. Is delivery address different from item 1? ☐ Yes**If YES, enter delivery address below: ☐ No**3. Service Type**☒ Certified Mail☐ Express Mail☐ Registered☐ Return Receipt for Merchandise☐ Insured Mail☐ C.O.D.**4. Restricted Delivery? (Extra Fee)**☐ Yes**2. Article Number**

(Transfer from service label)

7004 0550 0000 1512 4932

1 EDMUND G. BROWN JR.
Attorney General of the State of California
2 MARK ZAHNER
Chief Prosecutor
3 State Bar No. 137732
BRIAN V. FRANKEL
4 Supervising Deputy Attorney General
State Bar No. 116802
5 1455 Frazee Road, Suite 315
San Diego, CA 92108
6 Telephone: (619) 688-6065
Fax: (619) 688-4200
7 Attorneys for STATE OF CALIFORNIA

FILED
San Francisco County Superior Court

JUL 10 2007
GORDON PARK LI, Clerk
BY Deputy Clerk

8 SUPERIOR COURT OF CALIFORNIA

9 COUNTY OF SAN FRANCISCO

10
11 **THE STATE OF CALIFORNIA, ex rel.**
12 **JAYDEEN VICENTE and JAYDEEN**
VICENTE Individually,

13 **Plaintiffs,**

14 **v.**

15 **ELI LILLY AND COMPANY,**

16 **Defendants.**

CASE NO. CGC-07-463338

**STATE OF CALIFORNIA'S
NOTICE OF ELECTION TO
DECLINE INTERVENTION
PURSUANT TO GOVERNMENT
CODE SECTION 12652(c)(8)(D)(ii)**

NO HEARING REQUIRED

Dept: 212

Trial Date: None Set
Action Filed: May 11, 2007

**[FILED UNDER SEAL Pursuant to
Government Code sections 12652
subdivision (c)(2) and
and California Rules of Court, rule
243.6]**

23 **TO THE SUPERIOR COURT, STATE OF CALIFORNIA:**

24 PLEASE TAKE NOTICE that pursuant to Government Code section 12652(c)(8)(D)(ii), the
25 Attorney General of the State of California elects to decline intervention in this matter.

26 ///

27 ///

1 In accordance with the provisions of California Government Code section 12652(f)(1), the
2 Attorney General of the State of California requests that he be served with copies of all future
3 pleadings filed in this action.

4 Dated: July 9, 2007.

Respectfully submitted,

EDMUND G. BROWN JR.
Attorney General of the State of California
MARK ZAHNER
Chief Prosecutor
BRIAN V. FRANKEL
Supervising Deputy Attorney General



By BRIAN V. FRANKEL
Supervising Deputy Attorney General
Attorneys for STATE OF CALIFORNIA

DECLARATION OF SERVICE BY U.S. MAIL

Case Name: **THE STATE OF CALIFORNIA, ex rel. JAYDEEN VICENTE and JAYDEEN VICENTE v. ELI LILLY AND COMPANY**

Case No.: **CGC-07-463338**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 110 West "A" Street, Suite 1100, San Diego, California 92101.

On July 9, 2007, I served the attached **STATE OF CALIFORNIA'S NOTICE OF ELECTION TO DECLINE INTERVENTION** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States Mail at San Diego, California, addressed as follows:

**Nancy Hersh, Esq.
Hersh & Hersh, APC
601 Van Ness Avenue, Ste. 2080
San Francisco, CA 94102-6388
Counsel for Relator**

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on July 9, 2007, at San Diego, California.

Shakira N. Anderson

Declarant



Signature

CONFIDENTIAL

MC-060

ATTORNEY (Name, state bar number, and address): NANCY HERSH, ESQ., SBN 49091 HERSH & HERSH, A Professional Corporation 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102-6388 TELEPHONE NO.: 415-441-5544 FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR: <input checked="" type="checkbox"/> PLAINTIFF <input type="checkbox"/> OTHER (specify):	FOR COURT USE ONLY ENDORSED FILED <i>San Francisco County Superior Court</i> MAY 11 2007 GORDON PARK-LI, Clerk BY: PARAM NATT Deputy Clerk
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: CITY AND ZIP CODE: San Francisco, CA 94102 BRANCH NAME: Unlimited Jurisdiction PLAINTIFF: (UNDER SEAL) DEFENDANT: (UNDER SEAL)	
CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION	CASE NUMBER: CGC-07-463338

INSTRUCTIONS: This civil action is brought under the False Claims Act, Government Code section 12650 et seq. The documents filed in this case are under seal and are confidential pursuant to Government Code section 12652(c).

This Confidential Cover Sheet must be affixed to the caption page of the complaint and to any other paper filed in this case until the seal is lifted.

You should check with the court to determine whether papers filed in False Claims Act cases must be filed at a particular location.

Seal to expire on (date):

July 10, 2007

UNLESS:

(1) Motion to extend time is pending; or

(2) Extended by court order

1. The document to which this cover sheet is affixed is:

- a. ☐ Complaint for damages for violation of the False Claims Act
- b. ☒ Civil Case Cover Sheet (form 982.2(b)(1))
- c. ☐ Motion for an extension of time to Intervene
- d. ☐ Affidavit or other document in support of the motion for an extension of time
- e. ☐ Order extending time to intervene (specify date order expires):
- f. ☐ Other order (describe):

g. ☐ Notice from the Attorney General of additional prosecuting authority that may have access to the file

h. ☐ Other (describe):

2. This Confidential Cover Sheet and the attached document must each be separately file-stamped by the clerk of the court.

Date: May 11, 2007

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, Street number, and address): NANCY HERSH, ESQ. HERSH & HERSH, A Professional Corp. 501 Van Ness Avenue, Suite 2080 San Francisco, CA 94102-6396 TELEPHONE NO.: (415) 441-5544 FAX NO.: ATTORNEY FOR (Name): Plaintiff		CALIFORNIA STATE BAR NO.: 49091 <div style="text-align: center; border: 1px solid black; padding: 5px; margin-top: 10px;"> ENDORSED FILED San Francisco County Superior Court MAY 11 2007 GORDON PARK-LI, Clerk BY: _____ PARAM NATT Deputy Clerk </div>
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: San Francisco, CA 94102 CITY AND ZIP CODE: BRANCH NAME: Unlimited Jurisdiction		CASE NUMBER: CGC-07-463338 JUDGE: DEPT:
CASE NAME: VICENTE V. ELI LILLY AND COMPANY		
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000) <input type="checkbox"/> Limited (Amount demanded is \$25,000 or less) <input type="checkbox"/> Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)		

Items 1-5 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PVPD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PVPD/WD (23) Non-PVPD/WD (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PVPD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input checked="" type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
--	--	--

2. This case ☐ is ☒ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- | | |
|--|--|
| a. <input type="checkbox"/> Large number of separately represented parties | d. <input type="checkbox"/> Large number of witnesses |
| b. <input type="checkbox"/> Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve | e. <input type="checkbox"/> Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court |
| c. <input type="checkbox"/> Substantial amount of documentary evidence | f. <input type="checkbox"/> Substantial postjudgment judicial supervision |
3. Type of remedies sought (check all that apply):
 a. ☒ monetary b. ☐ nonmonetary, declaratory or injunctive relief c. ☐ punitive
4. Number of causes of action (specify): **4**
5. This case ☐ is ☒ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: May 11, 2007

RACHEL ABRAMS

(TYPE OR PRINT NAME)

SIGNATURE OF PARTY OR ATTORNEY FOR PARTY

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 at seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

CASE NUMBER: CGC-07-53338 (UNDER SEAL) VS. UNDER SEAL

NOTICE TO PLAINTIFF

A Case Management Conference is set for

DATE: OCT-12-2007

TIME: 9:00AM

**PLACE: Department 212
400 McAllister Street
San Francisco, CA 94102-3680**

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference.

However, it would facilitate the issuance of a case management order **without an appearance** at the case management conference if the case management statement is filed, served and lodged in Department 212 twenty-five (25) days before the case management

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state.

ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A MANDATORY SETTLEMENT CONFERENCE OR TRIAL.
(SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

Superior Court Alternative Dispute Resolution Coordinator
400 McAllister Street, Room 103
San Francisco, CA 94102
(415) 551-3876

See Local Rules 3.6, 6.0 C and 10 D re stipulation to commissioners acting as temporary judges

**SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO**

400 McAllister Street, San Francisco, CA 94102-4514

Case No. _____

Plaintiff

v.

Defendant

**STIPULATION TO ALTERNATIVE
DISPUTE RESOLUTION**

The parties hereby stipulate that this action shall be submitted to the following alternative dispute resolution process:

- | | | |
|---|---|---|
| <input type="checkbox"/> Private Mediation | <input type="checkbox"/> Mediation Services of BASF | <input type="checkbox"/> Judicial Mediation |
| <input type="checkbox"/> Binding arbitration | | Judge _____ |
| <input type="checkbox"/> Non-binding judicial arbitration | | Judge _____ |
| <input type="checkbox"/> BASF Early Settlement Program | | |
| <input type="checkbox"/> Other ADR process (describe) _____ | | |

Plaintiff(s) and Defendant(s) further agree as follows:

_____ Name of Party Stipulating	_____ Name of Party or Attorney Executing Stipulation	_____ Signature of Party or Attorney
------------------------------------	--	---

<input type="checkbox"/> Plaintiff	<input type="checkbox"/> Defendant	<input type="checkbox"/> Cross-defendant	Dated: _____
------------------------------------	------------------------------------	--	--------------

_____ Name of Party Stipulating	_____ Name of Party or Attorney Executing Stipulation	_____ Signature of Party or Attorney
------------------------------------	--	---

<input type="checkbox"/> Plaintiff	<input type="checkbox"/> Defendant	<input type="checkbox"/> Cross-defendant	Dated: _____
------------------------------------	------------------------------------	--	--------------

_____ Name of Party Stipulating	_____ Name of Party or Attorney Executing Stipulation	_____ Signature of Party or Attorney
------------------------------------	--	---

<input type="checkbox"/> Plaintiff	<input type="checkbox"/> Defendant	<input type="checkbox"/> Cross-defendant	Dated: _____
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☐ Additional signature(s) attached



Superior Court of California County of San Francisco

Judicial Mediation Program

Introducing a new court alternative dispute resolution
program that provides judicial mediation of complex civil cases

The Judicial Mediation program offers mediation of complex civil litigation by a San Francisco Superior Court judge familiar with the area of the law that is the subject of the controversy. Cases that will be considered for participation in the program include, but are not limited to professional malpractice, construction, employment, insurance coverage disputes, mass torts and complex commercial litigation. Judicial mediation offers civil litigants the opportunity to engage in early mediation of a case shortly after filing the complaint in an effort to resolve the matter before substantial funds are expended. This program may also be utilized at anytime throughout the litigation process. The panel of judges currently participating in the program includes:

The Honorable David L. Ballati
The Honorable Anne Bouliane
The Honorable Ellen Chaitin
The Honorable John J. Conway
The Honorable Robert L. Dondero
The Honorable Ernest H. Goldsmith
The Honorable Curtis B. A. Karnow
The Honorable Patrick J. Mahoney

The Honorable Tomar Mason
The Honorable James J. McBride
The Honorable Kevin M. McCarthy
The Honorable John E. Munter
The Honorable Ronald Evans Quidachay
The Honorable A. James Robertson, II
The Honorable Mary E. Wiss

Parties interested in judicial mediation should file the Stipulation to Alternative Dispute Resolution form attached to this packet indicating a joint request for inclusion in the program and deliver a courtesy copy to Dept. 212. A preference for a specific judge may be indicated. The court Alternative Dispute Resolution Coordinator will facilitate assignment of cases that qualify for the program.

Note: Space is limited. Submission of a stipulation to judicial mediation does not guarantee inclusion in the program. You will receive written notification from the court as to the outcome of your application.

Superior Court Alternative Dispute Resolution
400 McAllister Street, Room 103, San Francisco, CA 94102
(415) 551-3876

Alternative Dispute Resolution (ADR) Information Package

Alternatives to Trial

**Here are some other ways to
resolve a civil dispute.**

The plaintiff must serve a copy of the ADR information package
on each defendant along with the complaint. (CRC 201.9(c))

**Superior Court of California
County of San Francisco**

Introduction

Did you know that most civil lawsuits settle without a trial?

And did you know that there are a number of ways to resolve civil disputes without having to sue somebody?

These alternatives to a lawsuit are known as alternative dispute resolutions (ADR). The most common forms of ADR are mediation, arbitration and case evaluation. There are a number of other kinds of ADR as well.

In ADR, trained, impartial persons decide disputes or help parties decide disputes themselves. These persons are called neutrals. For example, in mediation, the neutral is the mediator. Neutrals normally are chosen by the disputing parties or by the court. Neutrals can help parties resolve disputes without having to go to court.

ADR is not new. ADR is available in many communities through dispute resolution programs and private neutrals.

Advantages of ADR

ADR can have a number of advantages over a lawsuit.

- *ADR can be speedier.* A dispute often can be resolved in a matter of months, even weeks, through ADR, while a lawsuit can take years.
- *ADR can save money.* Court costs, attorneys fees, and expert fees can be saved.
- *ADR can permit more participation.* The parties may have more chances to tell their side of the story than in court and may have more control over the outcome.
- *ADR can be flexible.* The parties can choose the ADR process that is best for them. For example, in mediation the parties may decide how to resolve their dispute.
- *ADR can be cooperative.* This means that the parties having a dispute may work together with the neutral to resolve the dispute and agree to a remedy that makes sense to them, rather than work against each other.

- **ADR can reduce stress.** There are fewer, if any, court appearances. And because ADR can be speedier, and save money, and because the parties are normally cooperative, ADR is easier on the nerves. The parties don't have a lawsuit hanging over their heads for years.
- **ADR can be more satisfying.** For all the above reasons, many people have reported a high degree of satisfaction with ADR.

Because of these advantages, many parties choose ADR to resolve a dispute, instead of filing a lawsuit. Even when a lawsuit has been filed, the court can refer the dispute to a neutral before the parties' position harden and the lawsuit becomes costly. ADR has been used to resolve disputes even after a trial, when the result is appealed.

Disadvantages of ADR

ADR may not be suitable for every dispute.

- If ADR is binding, the parties normally give up most court protections, including a decision by a judge or jury under formal rules of evidence and procedure, and review for legal error by an appellate court.
- There generally is less opportunity to find out about the other side's case with ADR than with litigation. ADR may not be effective if it takes place before the parties have sufficient information to resolve the dispute.
- The neutral may charge a fee for his or her services.
- If a dispute is not resolved through ADR, the parties may have to put time and money into both ADR and a lawsuit.
- Lawsuits must be brought within specified periods of time, known as statutes of limitation. Parties must be careful not to let a statute of limitations run out while a dispute is in an ADR process.

NATIONAL REGISTERED AGENTS, INC.**SERVICE OF PROCESS SUMMARY TRANSMITTAL FORM**

To: MICHAEL J. HARRINGTON
 ELI LILLY AND COMPANY
 LILLY CORPORATE CENTER
 INDIANAPOLIS, IN 46285-0000

SOP Transmittal # CA51043

(800) 767-1553 - Telephone
 (609) 716-0820 - Fax

Defendant: ELI LILLY AND COMPANY
 (Entity Served)

Enclosed herewith are legal documents received on behalf of the above captioned entity by National Registered Agents, Inc. or its Affiliate in the State of CALIFORNIA on this 22 day of August, 2007. The following is a summary of the document(s) received:

1. **Title of Action:** Plaintiff and Defendant Under Seal (See Package)

2. **Document(s) served:**

<input checked="" type="checkbox"/> Summons	<input type="checkbox"/> Subpoena	<input type="checkbox"/> Injunction
<input checked="" type="checkbox"/> Complaint	<input type="checkbox"/> Third Party Complaint	<input type="checkbox"/> Notice of
<input type="checkbox"/> Petition	<input type="checkbox"/> Demand for Jury Trial	<input type="checkbox"/> Mechanics Lien
<input type="checkbox"/> Garnishment	<input type="checkbox"/> Default Judgement	<input type="checkbox"/> Other:

M. J. HARRINGTON

AUG 24 2007

3. **Court of Jurisdiction/** San Francisco County Superior Court, Unlimited Jurisdiction
Case & Docket Number: CGC-07-463330

4. **Amount Claimed, if any:**

5. **Method of Service** (select one):

<input checked="" type="checkbox"/> Personally served by:	<input checked="" type="checkbox"/> Process Server	<input type="checkbox"/> Deputy Sheriff	<input type="checkbox"/> U. S Marshall
<input type="checkbox"/> Delivered Via:	<input type="checkbox"/> Certified Mail	<input type="checkbox"/> Regular Mail	<input type="checkbox"/> Facsimile
	(Envelope enclosed)	(Envelope enclosed)	
<input type="checkbox"/> Other (Explain):			

6. **Date and Time of Service:** 8/22/2007 4:17:27 PM PST (GMT -8)

7. **Appearance/Answer Date:** 30 Days

8. **Plaintiff's Attorney:** Nancy Hersh
 (Name, Address & Telephone Number) Hersh & Hersh, A Professional Corporation
 601 Van Ness Avenue
 Suite 2080
 San Francisco, CA 94102
 (415) 441-5544

9. **Federal Express Airbill #** 790812034891

10. **Call Made to:** Not required

11. **Special Comments:**
 Confidential Civil Cover Sheet - False Claims Action

NATIONAL REGISTERED AGENTS, INC.

Copies To: FAX: 3172766221
 MICHAEL J. HARRINGTON
 LILLY CORPORATE CENTER

Transmitted by: Joan Petty

INDIANAPOLIS, IN 46285-0000

The information contained in this Summary Transmittal Form is provided by National Registered Agents, Inc. for informational purposes only and should not be considered a legal opinion. It is the responsibility of the parties receiving this form to review the legal documents forwarded and to take appropriate action.

ORIGINAL

MC-060

ATTORNEY (Name, state bar number, and address): NANCY HERSH, ESQ., SBN 49091 HERSH & HERSH, A Professional Corporation 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102-6388 TELEPHONE NO.: 415-441-5544 FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR: <input checked="" type="checkbox"/> PLAINTIFF <input type="checkbox"/> OTHER (specify):		FOR COURT USE ONLY ENDORSED FILED San Francisco County Superior Court MAY 11 2007 GORDON PARK-LI, Clerk BY: PARAMATT Deputy Clerk
SUPERIOR COURT OF CALIFORNIA, COUNTY OF SAN FRANCISCO STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: CITY AND ZIP CODE: San Francisco, CA 94102 BRANCH NAME: Unlimited Jurisdiction		
PLAINTIFF: [UNDER SEAL] DEFENDANT: [UNDER SEAL]		
CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION		
INSTRUCTIONS: This civil action is brought under the False Claims Act, Government Code section 12650 et seq. The documents filed in this case are under seal and are confidential pursuant to Government Code section 12652(c). This Confidential Cover Sheet must be affixed to the caption page of the complaint and to any other paper filed in this case until the seal is lifted. You should check with the court to determine whether papers filed in False Claims Act cases must be filed at a particular location.		CASE NUMBER: CGC-07-463338

INSTRUCTIONS: This civil action is brought under the False Claims Act, Government Code section 12650 et seq. The documents filed in this case are under seal and are confidential pursuant to Government Code section 12652(c). This Confidential Cover Sheet must be affixed to the caption page of the complaint and to any other paper filed in this case until the seal is lifted. You should check with the court to determine whether papers filed in False Claims Act cases must be filed at a particular location.	Seal to expire on (date): July 10, 2007 UNLESS: (1) Motion to extend time is pending; or (2) Extended by court order
---	---

1. The document to which this cover sheet is affixed is:
- a. ☐ Complaint for damages for violation of the False Claims Act
 - b. ☒ Civil Case Cover Sheet (form 982.2(b)(1))
 - c. ☐ Motion for an extension of time to intervene
 - d. ☐ Affidavit or other document in support of the motion for an extension of time
 - e. ☐ Order extending time to intervene (specify date order expires):
 - f. ☐ Other order (describe):
 - g. ☐ Notice from the Attorney General of additional prosecuting authority that may have access to the file
 - h. ☐ Other (describe):

2. This Confidential Cover Sheet and the attached document must each be separately file-stamped by the clerk of the court.

Date: May 11, 2007

UNDER
2

Eli Lilly and Company
c/o National Registered Agents, Inc.
2030 Main St., SUITE 1030
Irvine, CA. 92614

UNDER
SEAL



From: (800) 767-1553
National Registered Agents, Inc.
2030 Main Street
Suite 1030
Irvine, CA 92614

To: MICHAEL J. HARRINGTON (317) 433-7016
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER

INDIANAPOLIS, IN 462850000

Ref: CAS1043

DELIVERY ADDRESS (FedEx-EDI)
IRK # 7908 1203 4891 FORM 0201

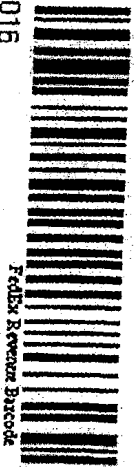
** 2DAY **

46285-IN-US

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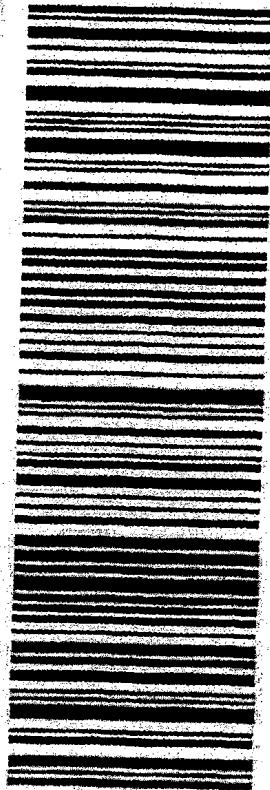
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Deliver by:
24AUG07



FedEx.

FedEx Revenue Barcode
CAD # 1124160
SHIP DATE: 22AUG07
WEIGHT: 1 LBS



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Name: HARRINGTON MICHAEL J
Telephone: 3174337016

D/C: 1093

Floor: 09

Bldg: 74

08/24/2007
09:18:40 AM



HERSHANDHERSH
A Professional Corporation

NANCY HERSH, ESQ., State Bar No. 49091
MARK E. BURTON, JR., ESQ., State Bar No. 178400
RACHEL ABRAMS, ESQ., State Bar No. 209316
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, 2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs

FILED
San Francisco County Superior Court

JUL 10 2007

GORDON PARK-LI, Clerk

BY:  CLERK

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

STATE OF CALIFORNIA *ex rel.*
JAYDEEN VICENTE and JAYDEEN
VICENTE Individually,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

§ CIVIL ACTION NO.: CGC-07-463338

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PROOF OF SERVICE

HERSHANDHERSH
A Professional Corporation

PROOF OF SERVICE

I, Alexandra Guardado, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6388.

On July 6, 2007, I served the following:

RELATORS' STATEMENT

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
1300 "I" Street
P.O. Box 944255
Sacramento, CA 94244-2550

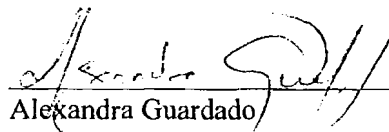
☒ (BY CERTIFIED U.S. MAIL RETURN RECEIPT REQUESTED) I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

☐ (BY PERSONAL SERVICE) I served by hand each such envelope to the addressee above.

☐ (BY OVERNIGHT DELIVERY) I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

☐ (BY FAX) I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on July 6, 2007, at San Francisco, California.


Alexandra Guardado

FILED
San Francisco County Superior Court

GORDON PARK-LI, Clerk

BY:  DATE: 

COUNTY OF SAN FRANCISCO

cor

HERSHANDHERSH
A Professional Corporation

PROOF OF SERVICE

I, Alexandra Guardado, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6388.

On July 6, 2007, I served the following:

RELATORS' STATEMENT

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004

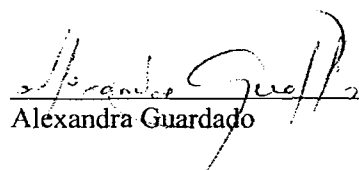
— (BY CERTIFIED U.S. MAIL RETURN RECEIPT REQUESTED) I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

X (BY PERSONAL SERVICE) I served by hand each such envelope to the addressee above.

— (BY OVERNIGHT DELIVERY) I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

— (BY FAX) I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on July 6, 2007, at San Francisco, California.


Alexandra Guardado

HERSHANDHERSH
A Professional Corporation

PROOF OF SERVICE

I, PORTLAND GRANT, declare:

I am employed in the City and County of San Francisco, California. I am over the age of 18 years and not a party to the within cause; my business address is 601 Van Ness Avenue, Suite 2080, San Francisco, California 94102-6396.

On May 11, 2007, I served the

COMPLAINT FOR DAMAGES [UNDER SEAL]; CIVIL CASE COVER SHEET; CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION; CONFIDENTIAL COVER SHEET-FALSE CLAIMS ACTION

in said action by placing a true copy thereof, enclosed in a sealed envelope, each envelope addressed as follows:

Office of the Attorney General
1300 "I" Street
PO Box 944255
Sacramento, CA 94244-2550

☒ (BY CERTIFIED MAIL-RETURN RECEIPT REQUESTED) I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

☐ (BY PERSONAL SERVICE) I caused such envelope to be delivered by hand to the offices of each addressee above.

☐ (BY OVERNIGHT DELIVERY) I placed a true and correct copy of the document(s) listed above enclosed in a sealed envelope(s), and causing said envelope to be delivered to an overnight delivery carrier with delivery fees provided for, addressed to the person(s) on whom it is to be served.

☐ (BY FAX) I transmitted via facsimile the document(s) listed above to the fax number(s) set forth above on this date before 5:00 p.m.

I declare under penalty of perjury that the above is true and correct. Executed on May 11, 2007, at San Francisco, California.


PORTLAND GRANT

NANCY HERSH, ESQ., State Bar No. 49091
 MARK E. BURTON, JR., ESQ., State Bar No. 178400
 RACHEL ABRAMS, ESQ., State Bar No. 209316
 HERSH & HERSH
 A Professional Corporation
 601 Van Ness Avenue, 2080 Opera Plaza
 San Francisco, CA 94102-6388
 (415) 441-5544

FILED
 San Francisco County Superior Court

MAY 11 2007

Attorneys for Plaintiffs

OCT 12 2007 -9⁰⁰AM

GORDON PARK-LI, Clerk
 BY: Param Matt
 Deputy Clerk

IMAGED

AUG 28 2007

DEPARTMENT 212

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

HERSHANDHERSH
 A Professional Corporation

<p>STATE OF CALIFORNIA <i>ex rel.</i> JAYDEEN VICENTE and JAYDEEN VICENTE Individually,</p> <p>Plaintiffs,</p> <p>v.</p> <p>ELI LILLY AND COMPANY,</p> <p>Defendant.</p>	<p>§ CIVIL ACTION NUMBER</p> <p>§</p> <p>§ CGC-07-463338</p> <p>§ COMPLAINT FOR DAMAGES</p> <p>§</p> <p>§</p> <p>§ [UNDER SEAL]</p> <p>§</p> <p>§</p> <p>§</p>
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Qui tam Plaintiff/Relator Jaydeen Vicente ("Plaintiff-Relator"), on behalf of the State of California and herself individually, for her Complaint against Defendant Eli Lilly and Company ("Lilly" or "Defendant Lilly") alleges based upon personal knowledge and relevant documents, as follows:

I. NATURE OF ACTION

1. This is an action to recover damages and civil penalties on behalf of the State of California arising from 1) intentionally false and/or fraudulent records caused to be presented and 2) statements and records caused to be made to get false claims paid by Defendant Lilly and/or its agents, employees and co-conspirators to California's Medicaid

1 Program, commonly known as Medi-Cal, in violation of the California False Claims Act,
2 Cal. Govt. Code §12650 *et seq.*

3 2. The instant matter arises in principal part from Defendant Lilly's
4 nationwide, coordinated deceptive off-label marketing and promotional practices for its
5 potent atypical antipsychotic Zyprexa. Specifically, Lilly devised, and successfully
6 implemented through its divisions of Zyprexa sales representatives, a marketing campaign
7 calculated to increase physicians' off-label use of Zyprexa within the State of California to
8 treat symptoms, mood disorders and patients within age demographics for which the drug
9 has not received FDA approval, nor which has been supported by the medical compendia
10 DRUGDEX, the American Hospital Formulary Service Drug Information or the United
11 States Pharmacopeia-Drug Information.

12 3. The conduct alleged herein shows a pattern of conduct designed to maximize
13 profits at the California Medicaid Program's expense.

14 4. Lilly's Zyprexa sales representatives were among primary resources used by
15 Lilly to dramatically increase Zyprexa sales for off-label uses to beneficiaries of
16 California's Medicaid program.

17 5. Lilly organized its Zyprexa sales force into several divisions. One such
18 division was a *Long Term Care* ("LTC") sales force consisting of 160 sales persons in
19 2000 to whom Lilly paid a generous salary and offered personal incentives such as bonus
20 programs in exchange for the unlawful and deceitful off-label promotion of Zyprexa in the
21 elderly demographic. Lilly's Zyprexa LTC sales representatives' sole objective was to
22 promote the potent and expensive antipsychotic within the LTC market for a litany of
23 unapproved and untested off-label medical uses for the explicit and illicit purpose of
24 increasing market share and revenues derived from this coveted patient population – which
25 the drug was not, and still is not, FDA-approved to treat.

26 6. Lilly provided extensive training and Zyprexa product support (including
27 advertising materials and exaggerated and misleading pro-Zyprexa studies) to its
28 "specialty" LTC sales force tailored to promoting Zyprexa's safety and efficacy to geriatric

1 healthcare providers (closed-end pharmacies, geriatric physicians and LTC facilities)
2 through misleading, deceptive and wanton means. In furtherance of its Zyprexa sales
3 scheme, Lilly also paid kickbacks masquerading as speaker fees, honoraria, unrestricted
4 educational grants, entertainment and other in-kind forms. Lilly disbursed its valuable
5 kickbacks with the understanding and specific intent that the geriatric healthcare providers
6 to which they were paid would increase their usage and/or dosage of Zyprexa in elderly
7 LTC facilities. Lilly engaged in this conduct purposefully, with the foreseeable impact of
8 increasing Zyprexa off-label sales revenues derived in principal part from Medicaid
9 programs all across the country, including Medi-Cal.

10 7. Lilly's illegal and zealous off-label over promotion of Zyprexa was
11 calculated to increase sales of Zyprexa in the elderly population for dementia symptoms,
12 agitation, insomnia and many other generic symptoms with reckless disregard for the safety
13 of the elderly patients prescribed the drug for such untested and unapproved uses which
14 Lilly targeted in its off-label marketing campaign.

15 8. Plaintiff-Relator has personal knowledge that Lilly engaged in the Zyprexa
16 off-label promotional effort in Long Term Care ("LTC") facilities and in primary care
17 physicians' offices in the State of California as well as nationwide, as she was employed by
18 Lilly as a LTC sales representative in the Northern California region.

19 9. Lilly's illegal Zyprexa marketing campaign was calculated to, and did, cause
20 billions of dollars of Zyprexa to be prescribed off-label to vulnerable, elderly long term care
21 nursing home residents and adults (who at most were depressed or presented with other
22 mood-related symptoms or illnesses) since Lilly's drug was released on the prescription
23 drug market in 1996. These expensive prescription purchases were funded, in whole or in
24 part, principally by government-funded healthcare programs including Medi-Cal.

25 10. Lilly's off-label LTC Zyprexa scheme succeeded. Lilly's LTC sales force
26 was the most successful of all Lilly's Zyprexa sales divisions. Specifically, Plaintiff-
27 Relator gained personal knowledge from Lilly corporate employees during Lilly's regional
28 and national sales conferences and from the sales data Lilly made available to her, that the

1 Zyprexa revenues generated per LTC sales representative far exceeded the Zyprexa
2 revenues generated per sales representative in any of its other Zyprexa sales division.

3 11. The purchases of the billions of dollars of dangerous, potent off-label
4 Zyprexa prescriptions in California were funded in principle part by and through the, *inter*
5 *alia*, Medi-Cal program. The State of California would not have funded millions of dollars
6 of Zyprexa purchases since the drug's launch in 1996 but for Lilly's unlawful, intentionally
7 deceitful and aggressive marketing tactics alleged herein.

8 12. Lilly's conduct endangered the health of Medi-Cal beneficiaries by placing
9 them at great risk of harm of developing serious, irreversible and even life-threatening side
10 effects that were known to Lilly at all times relevant to this Complaint, but which Lilly
11 intentionally concealed to protect its windfall of billions of dollars of annual Zyprexa sales
12 revenues.

13 13. Hundreds of thousands of Medi-Cal beneficiaries have now and continue to
14 fall victim to serious, irreversible diseases and or potentially life threatening medical
15 conditions including diabetes and hyperglycemia, in addition to the substantially increased
16 risk of death for certain patients, especially elderly patients with dementia, as a direct and
17 proximate cause of Lilly's illegal and capricious Zyprexa marketing tactics.

18 14. The California False Claims Act (Cal. Gov. Code §§ 12650 et seq.) permits
19 any person discovering a fraud perpetrated against the State of California to bring an action
20 for herself and for the State of California and to share in any recovery. Plaintiff-Relator
21 commences this *qui tam* action individually and on behalf of the State of California to
22 recover treble damages and civil penalties under the California False Claims California
23 False Claims Act, Cal. Gov. Code §§ 12650 et seq.

24 15. Although unfortunately, California's False Claims Act does not provide for a
25 recovery of the exorbitant medical costs to treat the diseases and afflictions Lilly knew
26 Zyprexa would cause, Plaintiff-Relator, on behalf of the State of California, seeks redress
27 against Lilly under the California False Claims Act for each of the hundreds of thousands
28 false claims for reimbursement for the prescription cost of Zyprexa Lilly intentionally and

1 willfully caused to be submitted to the Medi-Cal program.

2 **II. PARTIES**

3 16. Plaintiff-Relator brings this action on behalf the State of California to
4 remedy the millions of dollars its Medicaid program has been fraudulently induced to pay
5 as a result of false Zyprexa reimbursement claims submitted by, and caused to be submitted
6 by, Defendant Lilly. The State of California and Plaintiff-Relator Vicente will be
7 collectively referred to as "Plaintiffs."

8 17. Plaintiff-Relator Vicente is a citizen of the United States and resident of the
9 State of California. She resides at 7 Castle Hill Court, Vallejo, CA, 94591. Plaintiff-
10 Relator Vicente was employed by Lilly for three years beginning in February 2000 as a
11 Long Term Care Pharmaceutical Representative in the State of California. In this capacity,
12 Lilly trained, paid and directed Plaintiff-Relator to promote Zyprexa off-label to treat
13 elderly LTC skilled nursing facility residents in Northern California. Lilly offered Zyprexa
14 selling incentives to Plaintiff-Relator by structuring a bonus program available to her based
15 upon sales revenues of Zyprexa generated in her territory from LTC sales.

16 18. Defendant Eli Lilly and Company is an Indiana corporation and has its
17 principle place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.
18 At all times relevant hereto, Lilly was engaged in the business of licensing, manufacturing,
19 distributing, promoting and/or selling, either directly or indirectly, the pharmaceutical
20 prescription drug Zyprexa throughout the State of California and the United States, through
21 its third party agents and/or employees, including its LTC sales force and its primary care
22 physician sales divisions.

23 **III. FILING UNDER SEAL**

24 19. In accordance with California False Claims Act, Cal. Gov. Code
25 §12652(c)(2) and California Rules of Court, Rule 2.570, this complaint is filed *in camera*
26 and will remain under seal and will not be served on the Defendant Lilly until the Court so
27 orders. A copy of the complaint and written disclosure of substantially all material
28 evidence and information the Plaintiff possesses have been served on the State of California

1 pursuant to California False Claims Act, Cal. Gov. Code §12652(c)(3).

2 **IV. ORIGINAL SOURCE**

3 20. Through her employment as Lilly "specialty" LTC sales representative
4 assigned to the Northern California region, Plaintiff-Relator Vicente was trained and
5 employed by Lilly to promote Zyprexa for off-label uses, specifically, for use in the elderly
6 LTC demographic, as is alleged with particularity *infra*, Plaintiff-Relator acquired a wealth
7 of direct, independent and non-public knowledge of Lilly's unlawful acts described in this
8 Complaint.

9 21. Plaintiff-Relator gained personal knowledge of Lilly's kickback payments to
10 physicians made for the purpose, and with the intent to, induce those physicians (both
11 geriatric physicians and PCPs) to prescribe Zyprexa to his or her Medicaid beneficiary
12 patients.

13 22. Plaintiff-Relator has personal knowledge of Lilly's corporate endorsement of
14 this unlawful national off-label Zyprexa marketing scheme for the LTC market as well as
15 other markets including primary care and also has personal knowledge of the specific Lilly
16 corporate personnel responsible for implementing Zyprexa's off-label marketing.

17 23. Accordingly, Plaintiff-Relator is an "original source" of the non-public
18 information alleged in this Complaint within the meaning of California False Claims Act,
19 Cal. Gov. Code §12652(d)(3)(A) and (B), Plaintiff-Relator is concurrently providing to the
20 State Attorney General a disclosure statement summarizing and supported by known
21 material evidence in accordance with the provisions of California False Claims Act, Cal.
22 Gov. Code §12652(c)(3).

23 **V. JURISDICTION**

24 24. This Court has jurisdiction over the subject matter of this civil action. The
25 State of California is a named plaintiff.

26 25. This Court has jurisdiction over Defendant Lilly because the drug company
27 can be found in, is authorized to transact business in, and is now transacting business in the
28 State of California.

1 **VI. THE MEDI-CAL AND MEDICARE PART D PRESCRIPTION DRUG**
2 **REIMBURSEMENT BENEFIT**

3 **A. The Medi-Cal Program**

4 29. Title XIX of the Social Security Act is a program that provides medical
5 assistance for certain individuals and families with low incomes and resources. The
6 program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture
7 between the Federal and State governments to assist States in the provision of adequate
8 medical care to eligible needy Americans. Among the groups of people served by
9 Medicaid are eligible low-income parents and children. Among the health benefits funded
10 by Medicaid up until January 1, 2006 was funding for the prescription drug needs of the
11 Medicaid program beneficiaries.

12 30. At all times relevant to the Complaint, in most states, Medicaid was an open-
13 ended federal-state matching program. The federal government contributes a fixed
14 percentage of the state's Medicaid costs each year; however, the exact percentage the
15 federal government contributes varies year to year using a formula that takes into account
16 the state's per capita income relative to the national per capita income.

17 31. The percentage of state contribution the funding of prescription drug
18 purchases, and all other covered Medicaid health benefits, typically amounted to at least
19 40% at all times relevant to the complaint.

20 **B. The Medicare Part D Program**

21 32. Medicare is a government financial health insurance program administered
22 by the Social Security Administration of the United States. The health insurance provided
23 to beneficiaries of the Medicare insurance program is paid in whole or in part by the United
24 States.

25 33. Medicare was promulgated to provide payment for medical services, durable
26 medical equipment and other related health items for individuals 65 and over. Medicare
27 also makes payment for certain health services provided to additional classes of needy
28 classes of individual healthcare patients pursuant to federal regulation.

1 34. On December 8, 2003, Congress enacted the Medicare Prescription Drug,
2 Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created
3 new outpatient prescription drug coverage under Medicare ("Medicare Part D").

4 35. Medicare Part D went into effect on January 1, 2006. The Program is
5 administered by the United States Department of Health and Human Services, Centers for
6 Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who
7 received prescription drug coverage under Medicaid in addition to Medicare coverage for
8 other health care in 2005, enrollment in Medicare Part D was compulsory. Such
9 beneficiaries were automatically switched to Part D plans for 2006 and commenced
10 receiving comprehensive prescription drug coverage under Medicare Part D.

11 36. Pursuant to the Medicare Part D Program, states, including the Plaintiff State
12 of California provide funding for the purchases of beneficiaries of that program's
13 prescription drugs through what is commonly referred to as "claw back" provisions.

14 **C. Reimbursement Limits on Off-Label Drug Prescriptions**

15 37. Although Medi-Cal is administered by the State of California, Medi-Cal
16 adheres to federal guidelines. Federal statutes and regulations restrict the drugs and drug
17 uses that the federal and state governments will pay for Medicaid programs.

18 38. The Medicaid program includes individualized provisions, by statute and
19 regulation, concerning reimbursement for prescription drugs, drug utilization review, the
20 eligibility of various drugs for federal financial participation ("FFP"), price controls on
21 prescription drugs and drug manufacturer rebate agreements.

22 39. According to the Social Security Act, the State of California is entitled to
23 FFP for reimbursement of pharmaceuticals for covered patient drugs. 42 U.S.C.A. §1396r-
24 8. The definition of a "covered outpatient drug" is limited to those drug prescribed to treat
25 medically excepted indications. 42 U.S.C.A. 1396(k)(3). A medically accepted indication
26 is any use approved by the FDA, or supported by one of the three specifically identified
27 compendia. *Id.* (k)(6). The compendia are the American Hospital Formulary Service Drug
28 Information, the United States Pharmacopeia-Drug Information and the Drugdex